

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.*
JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFF-RELATOR'S MOTION TO COMPEL THE
DISCLOSURE OF LEGAL ADVICE

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 2

I. The Court Already Considered and Rejected Relator’s Arguments When It
Decided Relator’s January 28, 2022 Motion to Compel..... 2

II. Relator Does Not Identify Any New Circumstances That Warrant Revisiting the
Court’s April 7, 2022 Order..... 4

III. Janssen’s Position Is Clear and Entirely Consistent With the Court’s Prior Orders. 7

LEGAL STANDARD..... 7

ARGUMENT 8

I. As the Court Previously Ruled, Janssen Has Not Impliedly Waived Privilege by
Providing Non-Privileged Information about the PRC in Response to Relator’s
Discovery Requests..... 8

II. As The Court Previously Ruled, Janssen’s Assertion That It Acted in Good Faith
Does Not Waive Privilege. 13

III. It Is Premature to Make Admissibility Determinations. 17

CONCLUSION..... 17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Bacchi v. Mass. Mut. Life Ins. Co.</i> , 110 F. Supp. 3d 270 (D. Mass. 2015)	10, 13
<i>Bancinsure, Inc. v. Peoples Bank of the South</i> , No. 11-CV-78, 2012 WL 139208 (S.D. Miss. Jan. 18, 2012)	12
<i>Banco do Brasil, S.A. v. 275 Wash. St. Corp.</i> , No. 09-11343, 2011 WL 3208027 (D. Mass. July 27, 2011)	8, 9, 10, 11
<i>In re Cnty. of Erie</i> , 546 F.3d 222 (2d Cir. 2008).....	12
<i>DR Distribs., LLC v. 21 Century Smoking, Inc.</i> , No. 12-CV-50324, 2015 WL 5123652 (N.D. Ill. Sept. 1, 2015)	9
<i>In re Intuniv Antitrust Litig.</i> , No. 16-CV-12653, 2021 WL 10362709 (D. Mass. Mar. 3, 2021).....	10
<i>In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)</i> , 348 F.3d 16 (1st Cir. 2003)	8
<i>U.S. ex rel. Patzer v. Sikorsky</i> , 575 F. Supp. 3d 1032 (E.D. Wis. 2021).....	12
<i>U.S. ex rel. Schutte v. SuperValu Inc.</i> , 598 U.S. 739 (2023).....	15
<i>United States v. Desir</i> , 273 F.3d 39 (1st Cir. 2001).....	7, 8
<i>United States v. White</i> , 887 F.2d 267 (D.C. Cir. 1989).....	9

INTRODUCTION

In the two years since losing her first motion arguing that Janssen had waived the attorney-client privilege, Relator has been looking for an opportunity to relitigate the issue. She has repeatedly attempted to lay trip wires—through numerous discovery requests, motions to compel, and hours of deposition questioning designed to probe the line between privileged and non-privileged information—in an apparent attempt to force Janssen to stumble so Relator could claim that Janssen has now waived privilege. As Janssen told the Court in November 2022, Relator’s discovery demands were “an attempt by Relator to force Janssen to waive privilege.” ECF No. 334 at 20. Despite these endless efforts, her attempts have failed.

Relator’s second motion arguing that Janssen has waived the attorney-client privilege relies on the same facts and arguments already rejected by this Court. This is because, in response to Relator’s campaign to force Janssen to waive privilege, Janssen reacted by (1) asserting through unequivocal language in response to every one of Relator’s discovery demands that Janssen was neither relying on nor implying anything about whatever privileged advice may or may not have been provided, (2) producing only non-privileged information requested by Relator, consistent with the Court’s Order denying Relator’s motion, and (3) withholding privileged information and providing an appropriate privilege log.

In other words, Janssen has acted consistently with the Court’s April 7, 2022 Order, which held that (1) Janssen did not waive the attorney-client privilege by producing non-privileged policies and approval forms from Janssen’s Promotional Review Committee (“PRC”) in response to Relator’s requests for production, and (2) Janssen did not waive privilege by asserting the affirmative defense that it acted in good faith by adhering to an internal compliance process. ECF No. 303 at 2–4.

Relator's motion now seeks to upend that Order despite the fact that Janssen has never produced or relied upon privileged material and has constantly explained that it does not intend to do so. Recognizing that Janssen has not expressly relied on the advice of counsel, Relator once again asks the Court to "infer[]" that Janssen waived the attorney-client privilege by providing non-privileged information in response to Relator's discovery demands. ECF No. 427 at 10–12. However, because Janssen carefully adhered to the Court's decision, Relator's motion recycles the facts and arguments the Court considered two years ago when it denied Relator's first motion, including the PRC policies and approval forms attached to that motion. Relator's motion does not identify a single intervening change in the facts or the law that would support reversal of the Court's well-supported decision. Relator's renewed motion should be denied.

BACKGROUND

I. The Court Already Considered and Rejected Relator's Arguments When It Decided Relator's January 28, 2022 Motion to Compel.

The arguments and facts addressed in Relator's Motion are nearly identical to those in her prior motion to compel. There, as here, Relator argued that Janssen placed its counsel's advice at issue and waived privilege in two ways.

First, in both motions, Relator argues that Janssen waived privilege by producing evidence showing that its PRC reviewed and approved the programs at issue in this case. *Compare* ECF No. 264 at 17 ("Janssen is attempting to use the PRC approvals as evidence that it determined providing the various IOI Support services and programs was legal"), *with* ECF No. 427 at 11 (Janssen is "selectively present[ing] evidence of its attorneys' reviews and approvals to create inferences that the PRC attorneys reviewed whether the IOI Support violated the AKS and subsequently approved the provision of the IOI Support"). In her prior motion, Relator relied on

the PRC's SOPs and approval forms, ECF Nos. 264-4 (SOPs), 264-6 & 264-7 (Approval Forms), which she relies on again in her current motion, ECF Nos. 427-08 to 427-15.

The Court rejected Relator's argument. In doing so, it recognized that the PRC materials were not privileged, observing that "the PRC documents appear to show nothing more than that a lawyer reviewed the company's promotional materials within the context of the company's compliance procedures, and the documents do not appear to disclose the substance of any privileged communication." ECF No. 303 at 2–3. The Court found that Janssen's assertion that it acted in good faith by maintaining and adhering to the PRC review process, coupled with the production of PRC materials, was "not sufficient to trigger a finding of implied waiver." *Id.* at 4.

Second, in both motions, Relator argues that Janssen waived privilege by asserting an affirmative defense that it acted in good faith. *Compare* ECF No. 264 at 19 ("Janssen has put forth affirmative defenses that it acted based on its own subjective good faith belief that its actions were lawful."), *with* ECF No. 427 at 18 ("Janssen is in fact asserting an affirmative defense that, at the time that it was providing the IOI Support, it had a good faith belief that the services were lawful."). In the April 2022 Order, the Court rejected this argument, explaining that "[i]f defendant merely asserts that the procedural measures it took to comply with the law demonstrate that it acted in good faith, then '[t]he plaintiff does not need to discover counsel's privileged communications to test whether [the] defense has any merit.'" ECF No. 303 at 3 (quoting *Bacchi v. Mass. Mut. Life Ins. Co.*, 110 F. Supp. 3d 270, 278 (D. Mass. 2015)).

Finally, the Court appropriately emphasized that its prior Order was a "discovery ruling, not a determination as to the admissibility of the evidence of the PRC review at trial." *Id.* at 4. The Court recognized that although Janssen could, theoretically, waive privilege if it "expressly"

advanced arguments later in the case that placed privileged material at issue, Janssen had not yet done so. *Id.* Nothing has changed.

II. Relator Does Not Identify Any New Circumstances That Warrant Revisiting the Court's April 7, 2022 Order.

Relator's Motion is based on the same arguments the Court rejected previously, and she has not identified any changed circumstances that warrant a different result. As before, the case is still in discovery, and Janssen has not taken any affirmative steps to place privileged legal advice at issue. To the contrary, Janssen has protected privilege at every turn. Janssen has repeatedly, explicitly, and unambiguously refused to provide privileged information in response to Relator's discovery requests and has stated that it does not intend to rely on whatever privileged legal advice may or may not have been provided. *See* Def. Ex. 1 (collecting examples). Despite this, Relator once again asks the Court to determine that Janssen has waived its privilege by (1) producing non-privileged documents (while withholding and logging privileged ones) in response to Relator's discovery requests; (2) allowing non-privileged responses to Relator's deposition questions (while instructing witnesses not to disclose privileged information); and (3) providing non-privileged information in response to Relator's interrogatories.

As explained in greater detail below, all Janssen has done in each instance is comply with its discovery obligations in a manner that is consistent with the Federal Rules of Civil Procedure and this Court's prior rulings.

Document Productions: In her 2022 motion, as now, Relator claimed that Janssen's production of responsive, non-privileged documents related to the PRC resulted in an implied waiver because the PRC forms purportedly implied that PRC attorneys approved the legality of the IOI Support. ECF No. 264 at 18–20. All ten of the documents attached to Relator's current

motion are merely the same type of non-privileged PRC records attached to and relied on in Relator's prior motion: *i.e.*, PRC policy documents and approval forms. *Compare* ECF Nos. 264-4 to 264-7, *with* ECF No. 427-4 to 427-5 & 427-8 to 427-15. The Court already found that Janssen's production of these documents did not waive privilege. *See* ECF No. 303 at 2–3 (explaining that the PRC documents show only that a lawyer “reviewed the company’s promotional materials within the context of the company’s compliance procedures, and . . . do not appear to disclose the substance of any privileged communication.” (citing *Banco do Brasil, S.A. v. 275 Wash. St. Corp.*, No. 09-11343, 2011 WL 3208027, at *2 (D. Mass. July 27, 2011))).¹

Deposition Testimony: Relator also asserts that Janssen waived privilege by allowing deposition witnesses to provide non-privileged responses *to questions posed by Relator’s counsel* about the PRC process. Since the Court’s April 7, 2022 Order, Relator has deposed four current or former Janssen employees. Relator’s counsel spent hours—amounting to hundreds of pages of testimony—asking the witnesses questions about the PRC, including the role of the attorney. At each deposition, Janssen’s counsel directed the witness not to respond to questions about any legal advice sought or received, including in connection with the PRC process. Of course, Janssen could not, and did not, stop witnesses from testifying about topics the Court has already determined are not privileged. For instance, Janssen allowed witnesses to answer questions about things that were clear from the non-privileged documents already produced, such as the history and role of the PRC, that an attorney sat on the PRC, the names of PRC reviewers, and that the PRC reviewed and approved promotional materials, including the at-issue programs.

¹ Janssen has explicitly stated throughout discovery that by producing non-privileged documents demanded by Relator, Janssen was “not disclosing or intending to imply anything about what legal advice may or may not have been provided.” Def. Ex. 1. In contrast, Janssen has properly withheld or redacted all documents containing substantive legal advice.

Throughout Relator's questioning, Janssen made clear that it was Relator, not Janssen, who was asking questions about attorney involvement in the PRC, while stressing on the record that Janssen was not seeking to introduce testimony about any legal opinions and would not let its witnesses respond to questions seeking privileged information. For example, when Relator's counsel asked a witness about the role of the attorney on the PRC, Janssen's counsel stated:

I think we've been very clear, including with filings to the Court, that Janssen is not waiving attorney-client privilege. We're not asserting advice of counsel. We're in a deposition where I can't control the questions that you choose to ask the witness. And you're asking a lot of questions that get into areas -- and I'm trying to draw the line at the appropriate point to protect privilege consistent with our determined effort not to waive privilege or assert an advice of counsel defense. I'm not asking the questions.

Def. Ex. 1 (Zalesky Dep. at 128:25–129:12). Due to Relator's repeated focus on the role of the PRC attorney in depositions, Janssen's counsel asserted a similar objection in each of the four depositions conducted by Relator since the Court's April 2022 Order. *See* Def. Ex. 1 at 2–4.

The suggestion that Janssen selectively waived privilege because it “allowed” witnesses to provide such testimony, ECF No. 427 at 10, is also belied by Relator's counsel's own representations during the depositions that, when asking about PRC-related matters, Relator was not seeking privileged information. For example, Relator's counsel stated that they were “simply seeking what was the process for reviewing these strategies and the lawfulness of these strategies” and “not looking for any information that wouldn't be on a privilege log.” Def. Ex. 1 (Marzullo Dep. at 156:11–13 & 160:24–161:1, respectively).

As discussed below, the responses cited by Relator clearly do not waive privilege.

Interrogatory Responses: In her 2022 motion, as now, Relator contended that Janssen waived privilege by relying on the PRC process in interrogatory responses. ECF No. 264 at 9–11 (attaching three sets of interrogatory responses as evidence that Janssen put privileged

communications at issue by relying on the legal review inherent in the PRC process). Thereafter, Relator secured a Court order forcing Janssen to supplement its interrogatory responses with additional non-privileged information. ECF No. 322 at 12–13. Relator now argues that by providing the non-privileged information disclosed in those responses, Janssen has impliedly waived privilege. As discussed below, Janssen’s interrogatory responses describing the good faith defense are based on objective facts and have nothing to do with any legal opinions.

III. Janssen’s Position Is Clear and Entirely Consistent With the Court’s Prior Orders.

Given that Relator is now filing a second motion about the exact same issues, for the Court’s consideration and ease of review, Janssen provides the following summary of its position. As explained below, this is entirely consistent with Janssen’s actions throughout this litigation, the relevant case law, and the Court’s April 7, 2022 Order.

Janssen is not, and has no intention of ever: (1) asserting an advice of counsel defense; (2) disclosing any privileged legal advice; (3) relying on any privileged legal advice; (4) asserting or implying that its attorneys determined the programs were legal; or (5) asserting a defense based on its subjective good faith belief that the programs were legal.

What Janssen is doing is reserving the right to: (1) argue that Relator cannot carry her burden of establishing scienter; and (2) argue that the objective facts support its good faith defense. Those objective facts have nothing to do with legal opinions or Janssen’s subjective belief that the programs were legal. As Janssen has said for years, Janssen reserves the right to assert that its good faith is demonstrated by the fact that it adhered to internal compliance protocols involving the PRC that in no way implicate legal advice.

LEGAL STANDARD

Whether an implied waiver has occurred requires the Court to conduct “a careful weighing of facts.” *United States v. Desir*, 273 F.3d 39, 46 (1st Cir. 2001). Implied waivers

“should not be applied cavalierly.” *Id.* To protect the sanctity of the attorney-client privilege, the implied waiver analysis must begin “with the unarguable proposition that the attorney-client privilege is highly valued . . . [and] courts should be cautious about finding implied waivers.” *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 23 (1st Cir. 2003). Indeed, “the need for this precise, fact-specific tamisage . . . reveals few genuine instances of implied waiver,” *id.* at 23, most of which involve an advice of counsel defense, *Banco do Brasil*, 2011 WL 3208027, at *3. As the Court has already found, Relator’s arguments do not present one of the rare instances of implied waiver.

ARGUMENT

I. **As the Court Previously Ruled, Janssen Has Not Impliedly Waived Privilege by Providing Non-Privileged Information about the PRC in Response to Relator’s Discovery Requests.**

Relator suggests the law requires Janssen to make a Hobson’s choice: either improperly refuse to provide non-privileged information in response to discovery requests addressing the role of lawyers, or waive the privilege. That is not the law. In the Court’s April 2022 Order, the Court held that Janssen would not waive if it produced only materials not protected by the attorney-client privilege and refrained from affirmatively “argu[ing] . . . that it relied in good faith on the opinions of its attorneys.” ECF No. 303 at 4. Janssen has followed those instructions. It has not asked witnesses questions about legal advice in any deposition, produced privileged materials, or affirmatively relied in any way on legal advice. Instead, Janssen has repeatedly made clear that it is not asserting an advice of counsel defense, and it is not implying anything about whatever legal advice may or may not have been provided. Janssen has been assiduous in protecting the boundaries of privilege, including through appropriate yet forceful objections during depositions and production of an extensive privilege log. *See* Def. Ex. 1.

Despite these efforts, Relator once again argues, as she did in 2022, that Janssen has affirmatively put legal advice at issue and impliedly waived privilege by providing non-privileged discovery responses that reference counsel's role on the PRC, or that confirm that, as part of Janssen's compliance process, the PRC reviewed and approved the programs at issue in this case.² ECF No. 427 at 9–10; ECF No. 264 at 18–20. However, Relator ignores the Court's holding that an implied waiver takes place only when “the party asserting the privilege place[s] protected information in issue for personal benefit through some affirmative act, and the court [finds] that to allow the privilege to protect against disclosure of that information would [be] unfair to the opposing party.” ECF No. 303 at 2 (quoting *In re Keeper of Recs.*, 348 F.3d at 24). Merely disclosing the fact that a legal review occurred or that lawyers approved a course of action in response to Relator's discovery requests does not equate to putting legal advice at issue. *Id.* at 2–3; see also *Banco do Brasil*, 2011 WL 3208027, at *2 (“Revealing the general topic of discussion between an attorney and client does not waive [attorney-client] privilege, unless the revelation also reveals the substance of a protected communication.”); *United States v. White*, 887 F.2d 267, 271 (D.C. Cir. 1989) (“An averment that lawyers have looked into a matter does not imply an intent to reveal the substance of the lawyers' advice.”); *DR Distribs., LLC v. 21 Century Smoking, Inc.*, No. 12-CV-50324, 2015 WL 5123652, at *6–7 (N.D. Ill. Sept. 1, 2015) (holding that evidence of defendant consulting with counsel before filing trademark application did not waive privilege, even though evidence could be susceptible to the inference that attorney “blessed” the application).

Janssen has not affirmatively placed privileged information at issue in this litigation and thus has not impliedly waived privilege. Put simply, allowing witnesses to provide non-

² Relator does not argue that Janssen has expressly waived privilege.

privileged answers to deposition questions posed by Relator, responding to interrogatories propounded upon Janssen with non-privileged information, and producing non-privileged documents in response to Relator’s discovery requests are not “affirmative acts” that put legal advice at issue. A party must “*voluntarily* put[] its attorney’s advice at issue.” *Bacchi*, 110 F. Supp. at 275 (emphasis added). Here, Janssen simply provided non-privileged documents and permitted non-privileged testimony sought by Relator, including as ordered by the Court. Indeed, it would have been improper for Janssen to refuse to provide such non-privileged information in response to Relator’s requests. Janssen has not relied on any of this discovery to argue that counsel concluded the programs were legal, and it has repeatedly stated that it does not intend to do so, including in the discovery responses relied upon by Relator. *See* Def. Ex. 1.

None of the categories of discovery identified by Relator plausibly demonstrates an intent to rely on privileged material:

First, as the Court has found previously, the non-privileged PRC documents produced by Janssen “show nothing more than that a lawyer reviewed the company’s promotional materials within the context of the company’s compliance procedures, and the documents do not appear to disclose the substance of any privileged communications.” ECF No. 303 at 2–3. Courts have repeatedly held that producing documents showing the objective fact of approval or review by counsel is not an affirmative act that places advice of counsel at issue. *See, e.g., Banco do Brasil*, 2011 WL 3208027, at *3 (“[T]he Bank is contending that the objective facts . . . will establish . . . that it satisfied its obligations to seek regulatory approval. The mere fact that the Bank believes it acted in good faith . . . , and that its counsel was involved in the process, does not constitute waiver.”); *In re Intuniv Antitrust Litig.*, No. 16-CV-12653, 2021 WL 10362709, at

*9 (D. Mass. Mar. 3, 2021) (permitting defendant to rely on non-privileged evaluations in which its counsel was involved without waiving privilege) (citing *Bacchi*, 110 F. Supp. 3d at 275).

Relator argues that producing these types of documents results in an implied waiver, pointing to the portion of the Court’s April 2022 Order stating that if Janssen “[a]ttempts to use the fact of the [the PRC] review in a manner that implies approval of legal counsel . . . [it] might trigger an implied waiver.” ECF No. 303 at 4; ECF No. 427 at 10–15. This argument fails for two reasons. As an initial matter, Court already held after reviewing these same arguments that Janssen’s “mere production of PRC materials[] is not sufficient to trigger a finding of implied waiver.” ECF No. 303 at 4. In addition, Janssen has not “attempted to use the fact of [the PRC] review in a manner that implies approval of legal counsel” in any way. To the contrary, while expressly saying it was doing no such thing, it has simply provided non-privileged information in response to Relator’s discovery requests. Nothing has changed to alter the Court’s conclusion.

Second, Janssen has not waived privilege by “allowing” witnesses to testify—in response to Relator’s persistent questioning—about the mere fact that, as a procedural matter, legal members of the PRC were involved in the review of the programs. That testimony revealed nothing more than “general topic[s] of discussion between an attorney and client” or “the objective fact[]” that Janssen complied with its internal policies requiring PRC review, neither of which waive privilege. *See Banco do Brasil*, 2011 WL 3208027, at *2–3. Moreover, the attorney-client privilege is not so feckless that Relator can trigger a waiver by soliciting non-privileged information through its own deposition questions, and then turn around and argue that

Janssen intends to rely on those responses to “imply” something about legal advice (*i.e.*, advice Janssen instructed the witnesses not to disclose on the basis of privilege).³

Third, the references to Janssen’s responses to Interrogatory Nos. 3 and 18 in Exhibit 1 to Relator’s motion do not remotely implicate privileged advice. Janssen merely responded to Relator’s questions with non-privileged information. Interrogatory No. 3 required Janssen to “[i]dentify each Employee who reviewed or analyzed the lawfulness of helping physicians open an IOI, including when each Employee performed the review or analysis and the Employee’s position at the time of such review or analysis.” ECF No. 427-2 at 10. Janssen responded accurately that, consistent with industry practice, it had a PRC and that it included certain lawyers, citing the non-privileged PRC SOPs. *Id.* at 10–15. The only other response identified in Exhibit 1 is the response to Interrogatory No. 18, which required Janssen to “identify when [Janssen] began and, if applicable, stopped directing Area Business Specialists (including Plaintiff) and/or any Outside Consultant to utilize [any of the 31 enumerated] presentation[s], resource[s], or program[s] in connection with providing IOI support to IOI Accounts.” ECF No. 427-3 at 20–21. In responding, Janssen explained that these programs “go through an approval process by Janssen’s PRC,” and then identified (by Bates number) over 250 non-privileged PRC-related documents where the information about when the programs were in use could be found.

Id. at 22–28. Again, this interrogatory response had nothing to do with any privileged advice

³ See *In re Cnty. of Erie*, 546 F.3d 222, 230 (2d Cir. 2008) (reversing finding of waiver and noting that “the fact that the deponent was not before a ‘decisionmaker or fact finder’... means that Respondents have not been placed in a disadvantaged position at trial”); *U.S. ex rel. Patzer v. Sikorsky*, 575 F. Supp. 3d 1032, 1045 (E.D. Wis. 2021) (“Winkler’s answering truthfully the government’s questions at a deposition could not result in at-issue waiver because the defendants had no control over the government’s questioning. If defendants used that testimony to support a claim that they thought their actions were legal, then perhaps at-issue waiver could occur.”); *Bancinsure, Inc. v. Peoples Bank of the S.*, No. 11-CV-78, 2012 WL 139208, at *2 (S.D. Miss. Jan. 18, 2012) (no waiver where “with both the deposition testimony and the interrogatory responses, the statements were made in response to questions posed by [opposing] counsel”).

Janssen may or may not have received. Rather, it reflected a painstaking effort to respond to Relator's interrogatory with non-privileged facts, along with an explanation of how the PRC documents were responsive to the request. These are facts, not a legal contention.

In summary, the testimony, documents, and interrogatory responses cited in Relator's Exhibit 1 disclose non-privileged facts demanded by Relator. That does not result in an implied waiver of privilege.

II. As The Court Previously Ruled, Janssen's Assertion That It Acted in Good Faith Does Not Waive Privilege.

Once again, Relator argues that Janssen's assertion of a good faith defense has impliedly waived attorney-client privilege. But the proper invocation of a good faith defense does not mean a defendant has waived privileged. As Relator concedes, ECF No. 427 at 13, merely "pleading a good faith defense" or "asserting the defenses of good faith and regulatory approval" does not waive privilege. *Bacchi*, 110 F. Supp. 3d at 275, 277–78. Among other things, privilege is not waived if a party's claim of good faith is based on the existence of "procedural measures it took to comply with the law." *See* ECF No. 303 at 3 (quoting *Bacchi*, 110 F. Supp. 3d at 278). Even "evidence of defendant consulting with counsel" is not sufficient to impliedly waive privilege, "even though evidence could be susceptible to the inference that [the] attorney 'blessed' the application." *Id.* (citing *DR Distributions*, 2015 WL 5123652, at *4). As discussed above, and demonstrated in Def. Ex. 1 hereto, Janssen has gone out of its way to avoid any implication that it is relying on legal advice or approval by legal counsel.

Relator's argument that Janssen has nevertheless impliedly waived privilege by asserting a good faith defense is based entirely on Relator's misconstruction of supplemental interrogatory responses served by Janssen nearly a year ago. ECF No. 427 at 18–21.

First, Relator claims Janssen impliedly waived privilege through the portion of its supplemental response to Interrogatory No. 3 block quoted in Relator’s brief. ECF No. 427 at 20.⁴ That response merely identified the PRC process using a direct quotation from the PRC’s SOPs. *See* ECF No. 427-2 at 12. That very same language from the SOPs was quoted in Relator’s prior motion, ECF No. 264 at 11, the SOPs were attached as Exhibit D to Relator’s prior motion, ECF No. 264-4, and Relator’s counsel quoted that very same language from the SOPs during oral argument on Relator’s prior motion, ECF No. 304 at 57. This was part of the Court’s analysis when it said “the PRC documents appear to show nothing more than that a lawyer reviewed the company’s promotional materials within the context of the company’s compliance procedures.” ECF No. 303 at 2–3.

Second, Relator contends that Janssen impliedly waived privilege through language in a supplemental response to Interrogatory No. 20 in March 2023 referring to Janssen’s “good faith belief that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute and False Claims Act.” ECF No. 427 at 19. Again, that language is entirely consistent with language in Janssen’s original response to Interrogatory No. 20 in March 2022, before the Court’s April 2022 Order. *See* Def. Ex. 9 at 9 (“Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute . . . and False Claims Act . . .”).

⁴ For avoidance of confusion, Relator’s brief implies that the quoted language appears in the response to Interrogatory No. 20. It does not. The language appears in the response to Interrogatory No. 3, served in October 2022, which Relator asserts, without support, was “effectively incorporated” in the supplemental response to Interrogatory No. 20 in March 2023.

Moreover, Relator is mischaracterizing Janssen’s interrogatory response through selective quotation. Neither the March 2022 nor the March 2023 versions of the interrogatory response has anything to do with legal opinions or Janssen’s subjective understanding of the law. For example, Relator’s brief quotes (in bold and italics) a sentence from page 37 of Janssen’s supplemental response to Interrogatory No. 20. ECF No. 427 at 19. That sentence is embedded in the middle of a long paragraph that is all about the “objectively reasonable” meaning of the statutes, case law and regulatory guidance. ECF No. 427-2 at 38.⁵ It has nothing to do with legal opinions or, for that matter, the PRC. The same position was asserted in Janssen’s response to that same interrogatory in March 2022. *See* Def. Ex. 9 at 10. Meanwhile, the portion of the response to Interrogatory No. 20 that involves the PRC states very simply: “Janssen’s good faith and reasonable efforts to comply with the Anti-Kickback Statute and False Claims Act are also supported by the existence and practices of the Promotional Review Committee.” ECF No. 427-2 at 40 (citing Janssen’s response to Interrog. No. 3).

Relator’s attempt to construe the response to Interrogatory No. 20 as suggesting that Janssen is relying on legal opinions is also refuted by Janssen’s explicit statement on the very same page of that interrogatory response that, by responding to that interrogatory, “*Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been*

⁵ At the time Janssen provided this response, it was seeking to preserve a scienter defense in FCA cases—based on actions consistent with an objectively reasonable interpretation of legal requirements—the viability of which was pending before the Supreme Court. Several circuit courts, including the Seventh Circuit, had held that if “a defendant’s acts were consistent with any objectively reasonable interpretation of the relevant law that had not been ruled out by definitive legal authority or guidance,” then a “defendant could [not] be held liable for ‘knowingly’ submitting a false claim, no matter what the defendant [subjectively] thought.” *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 748 (2023). The “objective reasonableness” defense expressly did not depend on what a defendant knew or believed at the time of the submission of the allegedly false claims, and therefore it did not implicate any legal advice. The Supreme Court ultimately rejected the Seventh Circuit’s reasoning, holding that “[f]or scienter, it is enough if [defendants] believed that their claims were not accurate.” *Id.* at 757.

provided, it is not asserting the advice of counsel defense and has not waived, and it has no intention of waiving, any applicable privilege.” ECF No. 427-2 at 38 (emphasis added).

As Janssen has said *ad nauseum* over the past two years, it is not relying on any legal opinions, and it has no intention of ever relying on whatever legal opinions may or may not have been provided. In responding to Relator’s discovery responses, Janssen has been explicit on that point. *See* Def. Ex. 1. Janssen is again explicit in a direct representation to the Court here. From Janssen’s perspective, Relator has been engaged in a determined effort to generate a record from which it could argue that Janssen intends to do the opposite and has thereby waived privilege. But, even taking Relator at face value, whatever concern it may have that in the future Janssen might attempt to rely on legal opinions in some impermissible way, that would not provide a basis for its current motion. To the contrary, the Court is fully capable of barring Janssen from asserting a position that is inconsistent with its explicit representations to the Court, and it is fully capable of excluding any evidence that might be offered to support such a position.⁶

At this point, Janssen is not taking any positions or introducing any evidence: Janssen is merely reserving the right to assert a good faith defense that is consistent with the Court’s April 2022 Order, and consistent with any future orders that may be entered by the Court.

⁶ Relator’s alternative request that the good faith defense be stricken is both premature and ignores that Janssen has already disavowed any impermissible good faith defense.

III. It Is Premature to Make Admissibility Determinations.

As set out above, Janssen has not taken any affirmative step to put attorney advice at issue and has disavowed any intent to do so; Relator's argument that Janssen may rely on such advice in the future is based on speculation; and if Janssen attempts in the future to do so, the Court can prohibit that and exclude any evidence offered to support such a position.

Meanwhile, Relator's position is that depositions have barely even begun. ECF No. 411 at 3 (responding to Janssen's request for a status conference and seeking leave to take at least 18 additional depositions). The parties should be ordered to complete discovery and, if there is ever any question about whether Janssen is asserting an impermissible position at summary judgment or trial, the Court can address it at that point. At this stage, however, any decision about the admissibility of evidence related to the PRC is premature. *See* ECF No. 303 at 4 (stating that the Court's April 2022 Order applies only to discovery, not to admissibility of evidence).

CONCLUSION

For the reasons set forth above, the Court should deny Relator's Motion.

Dated: February 7, 2024

Respectfully Submitted,

/s/ Jason C. Raofield

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 7th day of February, 2024.

/s/ Jason C. Raofield

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